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3/1/01 Patricia K. Kamen  
Date Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

SHIRLEY et al.

Serial No.: 09/187,661

Group Art Unit: 1653

Filing Date: November 6, 1998

Examiner: F. Moezie

Title: NOVEL IGF-I COMPOSITION AND ITS USE

**RESPONSE**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

The paper is presented in response to Paper No. 12, dated January 31, 2001, asserting that the Amendment filed on November 15, 2000 was non-responsive. In particular, the Office asserts that applicants have presented claims to a "new invention" based on the recitation of "a low salt-containing composition." In support of this assertion, the Office points to the description of the invention set forth at page 6 of the Amendment. However, applicants disagree with the Office's assessment that the new claims are directed to a different invention than the previous claims.

In particular, the terminology "low salt-containing syrup" was previously present in examined claim 2. Applicants, by way of the previous Amendment, essentially incorporated the substance of claim 2 into claim 1. Further, applicants eliminated

language which the Examiner explicitly objected to under 35 U.S.C. §112, second paragraph in an effort to accommodate the Office and hasten prosecution.

Moreover, applicants submit that the characterization of the invention at page 6 of the Amendment is indeed consistent with the previous invention (and the present invention) claimed. In particular, page 6 of the Amendment characterizes the invention as follows:

The present invention is directed to low salt-containing compositions that comprise biologically active human IGF-I or biologically active variant thereof in a concentration of at least about 250 mg/ml...The compositions comprise a highly concentrated, precipitated form of human IGF-I or variant thereof that has the consistency of a viscous syrup...

This definition of the invention is also found in the application at, e.g., page 4, lines 1-4. The consistency of the IGF-I of the invention inheres from the fact that the IGF-I is present at a concentration of at least 250 mg/ml and is "low salt-containing." See, e.g., page 3, lines 14-17 and page 4, lines 1-13, of the application as filed. Thus, applicants, by way of the previous amendment, eliminated language regarding inherent properties of the IGF-I composition and added language regarding salt content which was already present in claim 2. As explained in the specification, the concentration of IGF-I, as well as the salt content, is responsible for the "highly concentrated" form. Although applicants pointed out that the terminology "highly concentrated" was clearly defined in the application, this language was eliminated in response to the Office's rejections in order to hasten prosecution.

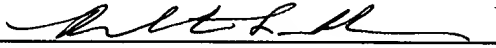
Applicants submit, therefore, that the amended and new claims are not directed to a "new invention" and that the previous Amendment was indeed responsive.

Please direct all further written communications regarding this application to:

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Respectfully submitted,

Date: 3/1/01

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